

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
UNITED STATES DISTRICT COURT**DISTRICT OF NEVADA**

TAMARA J. TOWNSEND,

Plaintiff

v.

ETHICON, INC. and JOHNSON &
JOHNSON,

Defendants

Case No.: 2:20-cv-01984-APG-DJA

**Order Denying Motion to Exclude Case
Specific Opinions of Dr. Michaels**

[ECF No. 53]

This case is one of thousands of cases that were joined in multidistrict litigation (MDL) in the United States District Court for the Southern District of West Virginia. That court conducted the MDL litigation in waves, with this case being one of the wave 12 cases. The case was recently remanded to this court from the MDL court with several motions pending, including the defendants' motion to limit the case specific testimony of plaintiff Tamara Townsend's expert, Dr. Paul Michaels. Townsend opposes.

The parties are familiar with the facts, so I do not repeat them here except where necessary. I deny the defendants' motion.

I. ANALYSIS

I adopt Judge Goodwin's prior articulation of the standard for reviewing motions challenging expert testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). See *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701-02 (S.D. W. Va. 2014).

////

////

1 **A. Qualifications**

2 The defendants argue that Dr. Michaels is not qualified to opine that their device, the
3 TVT Abbrevo, caused Townsend’s injuries because he is a pathologist, not a urologist,
4 gynecologist, or urogynecologist, and is not trained in gynecological pathology or
5 neuropathology. Townsend responds that Dr. Michaels is qualified by both training and
6 experience to testify about tissue response to foreign bodies generally and to polypropylene mesh
7 specimens specifically.

8 Dr. Michaels is board certified in anatomic pathology, clinical pathology, and
9 cytopathology, with a subspecialty focus on breast and gynecology pathology, as well as
10 cytopathology. ECF No. 57-4 at 2. “A pathologist is a clinician who provides diagnoses for
11 patient care based on the examination of specimens they receive and relevant clinical
12 information.” *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 712 (S.D. W. Va. 2014). Dr.
13 Michaels is qualified as a pathologist to opine that there is no other pathological cause for
14 Townsend’s injuries following a review of her medical records and examination of specimens of
15 the mesh and her tissue. He thus “based his opinions in large part on reliable pathology methods.
16 He reviewed clinical records, examined explanted specimens, considered possible causes of pain,
17 and came to a diagnostic conclusion.” *Eghnayem*, 57 F. Supp. 3d at 712. I therefore deny the
18 defendants’ motion on this basis.

19 **B. Reliability of Opinion Correlating Pain**

20 The defendants argue that Dr. Michaels’ opinion that there is a connection between
21 inflammation, fibrosis, and Townsend’s pain is unreliable because he has never tested his thesis
22 that mesh degradation leads to inflammation and scarring that causes pain. They also contend
23 that Dr. Michaels’ opinion is not based on reliable methodology because no inflammation was

1 observed in Young's specimen tissues, nor was there evidence of scar plating, scar bridging,
2 erosion, or extrusion in the specimens he examined. The defendants contend he misinterpreted
3 medical records rather than relying on his examination of the tissue specimens. Townsend
4 responds that Dr. Michaels' opinions are reliably based on his review of Townsend's explanted
5 mesh and tissues, as well as his review of her medical records, his experience as a pathologist,
6 and a review of the scientific literature.

7 To prepare his opinions, Dr. Michaels reviewed Townsend's medical records, slides of
8 tissue specimens explanted from Townsend, internal Ethicon documents, scientific literature, and
9 deposition testimony from this case. ECF No. 57-4 at 1. He identified where in the medical
10 records Townsend's doctors noted conditions such as mesh erosion, mesh exposure, weakened
11 tissue, and mesh penetration causing pain. *Id.* at 6, 8. He also examined 12 explanted tissue
12 samples and explained his related findings, including where he noted foreign body reaction,
13 bridging fibrosis, and scar plate formation in Townsend's specimens. *Id.* at 10-12, 17-38. The
14 defendants' challenges go to the weight of Dr. Michaels' testimony, not its admissibility, and the
15 defendants may cross examine him on these points. I deny this portion of the defendants'
16 motion.

17 **C. Degradation**

18 The defendants argue Dr. Michaels' opinion that the TVT Abbrevio mesh degraded while
19 in Townsend's body is unreliable because he has no knowledge or expertise regarding
20 degradation and he fails to take into account that specimens like the one removed from
21 Townsend are preserved in formalin, which causes stiffness. They also contend that his opinion
22 that degradation caused Townsend's injuries is unsupported by any scientific basis. Townsend
23

1 responds that his opinion is supported by his review of Townsend's slides on which he noted
2 degradation, as well as a review of her medical records, tissue samples, and scientific literature.

3 Dr. Michaels formed his opinion "using standard histopathology techniques, in addition
4 to other described histologic findings on routine light microscopy." ECF No. 53-1 at 10. He
5 "observed the surface layer of the Prolene-based device that was implanted in Ms. Townsend for
6 approximately 1 year, degraded while implanted in her body." *Id.* He "observed that the surface
7 of the mesh fibers was cracked, extending to the central core of the mesh space," and opined that
8 the degraded device's brittleness "can impact the biocompatibility of the device and result in
9 patient complications like those experienced by Ms. Townsend." *Id.* He based that opinion on
10 his prior experience examining mesh explants, his examination of Townsend's slides, and
11 identified scientific literature. *Id.*; ECF No. 57-3 at 5; 57-4 at 39-41. As discussed above, he is
12 qualified to render the opinion offered.

13 Additionally, Dr. Michaels' testimony reflected that he is aware that specimens are
14 sometimes delivered in formalin and he described that he was focused on "the pathophysiologic
15 fibrosis that draws the tissue together." ECF No. 57-3 at 12-13. He acknowledged that mesh can
16 "change shape after it's out of the body based on the circumstances that it was in both in vivo
17 and then outside." *Id.* at 13. And he explained that he has examined mesh samples both prior to
18 and after formalin fixation, and he understands that formalin may change tissues or synthetic
19 material, but "what is important is if there's any substantive changes to the tissues." *Id.* at 15, 18.
20 Whether he properly accounted for formalin in this case is a matter for cross examination, not a
21 basis to exclude his testimony. I therefore deny the defendants' motion on this basis.

22 ////

23 ////

1 **II. CONCLUSION**

2 I THEREFORE ORDER that the defendants' motion to limit the case specific testimony
3 of Dr. Paul Michaels (**ECF No. 53**) is **DENIED**.

4 DATED this 29th day of January, 2021.



6 ANDREW P. GORDON
7 UNITED STATES DISTRICT JUDGE
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23